Attachment RT-3.1 (maintain on-site)

Test Device Temperature Log

Testing Site: _____ City: _____

Testing Kits Location:_____

Type of Rapid Test Kits: ☐ OraQuick ☐ Uni-Gold ☐ INSTI ☐ Clearview

The high and low temperatures of the test kit storage area should be recorded using a digital thermometer with a temperature range memory that will display the warmest and coolest temperatures reached in the storage area in-between checks.

If temperature falls outside the allowable range, notify quality assurance coordinator immediately.

Allowable Temp Range:	from: ___ degrees F	to: ___ degrees F

Daily Temperature Record for Month:_____Year:_____

Date	Low	High	Initial	Date	Low	High	Initial
1				16			
2				17			
3				18			
4				19			
5				20			
6				21			
7				22			
8				23			
9				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			
				31			

Note any incidents and corrective actions taken below:

Corrective Action

Date:	

Quality Assurance Coordinator_____ Date:_____

Attachment RT-3.2 (maintain on-site)

Control Kit Temperature Log

Testing Site: _____ City: _____

Control Kits location:_____

Type of Rapid Test Control Kits: ☐ OraQuick ☐ Uni-Gold ☐ INSTI ☐ Clearview

The high and low temperatures of the control kit storage refrigerator should be recorded using a digital thermometer with a temperature range memory that will display the warmest and coolest temperatures reached in the refrigerator in between checks.

If temperature falls outside the allowable range, notify quality assurance coordinator immediately.

Allowable Temp Range:	from: ___ degrees F	to: ___ degrees F

Daily Temperature Record for Month:_____ Year:_____

Date	Low	High	Initial	Date	Low	High	Initial
1				16			
2				17			
3				18			
4				19			
5				20			
6				21			
7				22			
8				23			
9				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			
				31			

Note any incidents and corrective actions taken below:

	Corrective Action
Date:	

Quality Assurance Coordinator_____ Date:_____

Attachment RT-3.3 (maintain on-site)

Daily Rapid HIV Test Log

Test Site:_____ **Date of Testing:**_____

Type of Rapid Test: ☐ OraQuick ☐ Uni-Gold ☐ INSTI ☐ Clearview

Rapid Lab Counselor #	HIV Test form Number	Room Temperature	Time Test Started	Time Test Result Read	Rapid Test Result	Date Client Notified	Lot Number of Test Kit	Test Kit Expiration Date
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			
					☐ Reactive ☐ Neg ☐ Invalid ☐ No result			

Quality Assurance Coordinator:_____ **Date:**_____

Attachment RT-3.4 (maintain on site)

Control Kit Log

(If using multiple rapid testing technologies, use a separate log for each type of rapid testing device)

Test Site:________________________________ **Month/Year:**__________________

Control Lot #:_______________________ **Manufacturer's Expiration Date:**_____________

Date Kits Opened:___________________ ***Oraquick control kits are good for 8 weeks after opening.***

Type of Kit Controls: ☐ OraQuick ☐ Uni-Gold ☐INSTI ☐ Clearview

Date	Counselor #	NEG	HIV-1	HIV-2 (OraQuick and Clearview Only)	Reason for running controls
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	
		☐ Pass ☐ Fail	☐ Pass ☐ Fail	☐ Pass ☐ Fail	

Quality Assurance Coordinator:____ Date:_______________

Possible reasons for running controls: New Shipment, New Lot Number, Storage or Operating Temperature Out of Range, Arrived at Outreach Location, Facility Protocol

Attachment RT-3.5 (submit to SHP monthly)

HIV TESTING SUPPLY ORDER FORM

Contact Information (Agency conducting HIV Testing):

Testing Site Name:_____ Order Date:_____

Quality Assurance Coordinator:_____

Mailing Address: _____

City, State, Zip: _____ Phone Number: _____

Fax Number:_____ E-Mail Address:_____

CLIA Certificate #:_____ (Required for all rapid testing supplies) CLIA Expiration Date:_____

Please write the number of cases/boxes/packets needed. Please allow a minimum of 4 weeks for delivery or pick up. Some items may not be available at the time of order or available to your site. Agencies located within Region 1 will be notified when their order is ready for pick up.

LIST OF SUPPLIES	QUANTITY	# ORDERED	For SHP Use
HIV Test forms-Part 1	100 forms/packet		
Sites must have prior approval from OPH SHP before ordering any of the following items:			
OraQuick ADVANCE Rapid Test Kits	100 kits/box		
OraQuick ADVANCE Kit Control	1 kit/box		
Uni-Gold Recombigen Rapid Test Kits	20 kits/box		
Uni-Gold Kit Control	1 kit/box		
Clearview Complete Rapid Test Kits	25 kits/box		
Clearview Kit Control	1 kit/box		
INSTI Rapid Test Kits	24 kits/box		
INSTI Kit Control	1 kit/box		
Digital Memory Thermometer	Each		
Timer	Each		
XL Gloves ☐ Nitrile ☐ Latex	100/box		
L Gloves ☐ Nitrile ☐ Latex	100/box		
M Gloves ☐ Nitrile ☐ Latex	100/box		
S Gloves ☐ Nitrile ☐ Latex	100/box		
Workspace Covers	100/box		
Biohazard waste disposal bag	Each		
Sharps Container (limited availability)	Each		

Please fax this form to: OPH SHP PURCHASING & SUPPLIES COORDINATOR

Fax number: (504) 568-7044

For SHP Use Only:

SHP Staff Initials:_____ Date received:_____

Rapid Tests Lot #: _____ Rapid Tests expiration date:_____

Control Lot #:_____ Control kit expiration date:_____

Delivered to (name):_____ Date delivered: _____

Delivered to (name):_____ Date delivered:_____

Attachment RT-3.6 (to be completed by Regional HIV Coordinator and submitted as needed)

HIV Prevention Counseling, Testing and Referral (CTR) Rapid Site Assessment and Registration Form

All sites, whether fixed or mobile, must be registered with OPH SHP.
Please allow four (4) weeks for processing.

Type of Request (check one): □ **New Site** □ **Update Existing Site** □ **Drop Site**

Contact Information (Agency conducting CTR):

Agency:_____

Mailing Address: _____

City, State, Zip: _____

OPH Region: _____ Parish:_____

Phone Number:_____ Fax Number:_____

E-Mail Address:_____ CLIA Certificate #:_____

Executive Director Information:

Name:_____

Mailing Address: _____

City, State, Zip: _____

Phone Number: _____ Fax Number: _____

Executive Director's Email: _____

Prevention Manager Information:

Name:_____

Mailing Address: _____

City, State, Zip: _____

Phone Number: _____ Fax Number: _____

Prevention Manager's Email:_____

Quality Assurance Coordinator Information:

Name:_____

Mailing Address: _____

City, State, Zip: _____

Phone Number: _____ Fax Number: _____

Quality Assurance Coordinator's Email:_____

Site Information (location where CTR will be conducted):

Name of Site: _____

Site Address: _____

City, State, Zip: _____

Phone Number: _____ Fax Number: _____

Detailed Description of Site Type (i.e. clientele, hours of operation, services offered): _____

_____

_____

Detailed Description of Test Set-Up(i.e. how will confidentiality be assured, where in the building will testing happen, etc: _____

Type of Testing Requested (check all that apply):

□ Rapid Testing:_____ □ OraSure □ Blood (lab)

Date: _____ Observed by: _____

Check appropriate assessment of testing site:

Work space to process test:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Confidential setting:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Cleanliness:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Lighting:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Temperature control:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Supply storage:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Hand washing station:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Record keeping:	□ Acceptable	□ Conditional (describe)	□ Unacceptable
Waiting area:	□ Acceptable	□ Conditional (describe)	□ Unacceptable

Notations:_____

_____

_____

_____

For Office Use Only: Date request received:_____ Date visited:_____

Recommendation:_____

SHP Coordinator Initials: _____ CTR Supervisor's Initials:_____ Date logged into database:_____

Approved for: □ Rapid Testing: Primary Test_____ Second Test_____

Site #:_____ **Parent Site #:**_____

Attachment RT-3.7 (submit to SHP as needed)

Quality Assurance Coordinator Registration/Designation Form

All Agencies conducting Rapid HIV Testing in Louisiana must designate and register a Quality Assurance Coordinator. The Quality Assurance Coordinator should be a person with significant experience conducting rapid testing (6 months experience and a minimum of 200 rapid tests conducted) and familiar with storage and operating procedures/requirements of the rapid testing device(s) used at their agency.

Submit to SHP immediately whenever the designated Quality Assurance Coordinator changes or when updates/changes to his/her contact information occur.

Rapid Testing Site:_____Site Number:_____

Date Form Submitted:_____Submitter:_____

Reason for Submission:

____Newly Designated Quality Assurance Coordinator
____Change in Quality Assurance Coordinator's contact information
____Other, specify below:

_____
_____
_____

About the Designated Quality Assurance Coordinator:

Name*: _____
Title*: _____
Work Address*: _____
_____
_____
Counselor Number*: _____
Work Phone*: (____)_____
Cell: (____)_____
Alternate Phone (____)_____
Work Email*: _____
Alternate Email: _____

Number of Months/Years Experience with Rapid Testing:_____

***Areas marked with an asterisk are required fields**

Fax completed form to (504) 568-7044
Attention CTR Supervisor

Attachment RT-3.8 (maintain on site – for information only)

Steps to HIV Counseling and Testing Certification

Steps for Obtaining a Counselor Number:

1. Attend a combined HIV Prevention Counseling and Rapid Testing course in its entirety and leave with a certificate of participation.
2. After completing the HIV Prevention Counseling and Rapid Testing training and receiving a certificate of completion, there are two additional steps. First, a written test covering HIV prevention counseling, rapid testing skills, and protocol/paperwork must be passed. The dates, locations, and method of signing up for a class are outlined on www.hiv411.org. Secondly, all persons conducting CRT must successfully complete an observation session with the Regional Prevention Coordinator or other SHP Prevention staff as arranged by the Prevention Coordinator. Each person has two opportunities to pass the written test and the counselor observation. If the person fails either the test or the observation twice, they must go through the entire process again, beginning with training. Also, the written test must be passed before the observation can be scheduled.
3. Once the SHP Training Coordinator assigns a unique counselor number to the counselor, they are fully certified and may conduct CRT.

Steps for Registering a Rapid Testing Site:

1. Regional HIV Coordinator must conduct a site visit and make their recommendation on the site assessment and registration form. This form will then be given to the CT Supervisor.
2. If the site is favorably observed, CT Supervisor will assign a site number and mail a certificate with this number on it. A copy of this certificate must be kept on the site premises at all times.

Please Note: Meeting all counselor requirements does not automatically qualify your agency for site approval. Meeting all site requirements does not automatically qualify your agency for funding or free testing materials.

Attachment RT-3.9 (maintain on site-for information only)

Louisiana HIV Prevention Counseling and Rapid Testing Service Delivery Model

The following steps apply to testing with OraQuick, Clearview, and Uni-Gold when used as the first rapid test. *For those using INSTI as the first rapid test, collect the specimen and run that test after #3a below.

Step 1a - Introduce and Orient the Client to the Session

- Introduce yourself to the client.
- Assess client's readiness to receive the results on the same day.
- Offer options for testing (conventional or rapid).
- Describe the testing process, what type of specimen will be collected, how long the whole process will take, and what each of the three possible results mean.
- Explain to client that if a preliminary positive result is received, a second rapid test will be conducted.
- Address Partner Services, including informing the client that if results come back positive, a DIS will contact them to offer additional services.
- Offer anonymous and confidential options, and explain what each mean.
- Obtain Informed Consent.
- Provide appropriate subject information pamphlet for the rapid test being conducted.

Step 1b – Administer the Rapid Test

- Follow applicable universal precautions
- Clearly label the test device being used
- Demonstrate/facilitate specimen collection
- Start Timer

Step 2 – Identify Risk Behaviors and Circumstances

- Engage client in a discussion of risk behavior
- Assess client's previous experience with HIV testing and knowledge about HIV/AIDS
- Complete all but results section of HIV Test Form-Part 1

Step 3a – Identify Safer Goal Behaviors

- Give client information on relevant risk and harm reduction strategies
- Use relevant information pamphlets, brochures and/or brief videos
- Have client explain what he/she can do to reduce risk
- Assess client readiness to receive results can continue up until the timer goes off
- Allow time for client to process and respond

Step 3b – Interpret and Deliver the Test Result (after appropriate time as elapsed)

- Follow applicable universal precautions for handling rapid testing materials
- Interpret Test Result (use a second reviewer if needed and client is not present)
- Return to client and give the results immediately in a simple and direct fashion
- Allow time for client to process and respond

Step 4 – Develop Risk Reduction/Action Plan (can be initiated prior to delivery of test results but should be modified, as needed, after results are provided)

- Based on the results of the test and the client's risk profile, assist the client in developing an action plan to further protect their health and the health of their partners.
- Document risk reduction plan in client's file

Step 5 – Offer Referrals and Provide Support (can be initiated prior to delivery of test results but should be modified, as needed, after results are provided)

- Make appropriate referrals and negotiate plans to follow up with the client

Step 6 – Summarize and Close the Session

Attachment RT-3.10 (maintain on site-for information only)

Louisiana Office of Public Health HIV Prevention Counseling and Rapid Testing Skills Observation Form

All HIV prevention counselors and all prospective counselors conducting rapid HIV testing must submit a favorable observation prior to performing rapid testing on patients/clients. Counselors must be re-observed at least once per year thereafter and copies of all observation forms must be maintained in the counselor's personnel file.

Name of Counselor:		***Date Trained:***		***Counselor #:***		**Point Scale:** 0 = not done 5 = deficient 10 = proficient
Date and Time of Observation:		***Location of Observation:***				

FIRST: Conduct verbal test result quiz with prospective counselor: PASS or FAIL (circle one)
If the counselor passed, continue with observation, if they failed then stop here.

	Score	Comments
Counseling Skills-Before Rapid Test Is Run		
1. **Counselor offered options in testing procedures.**		
2. **Counselor carefully explained rapid testing and potential results.**		
3. **Counselor carefully explained confidential and anonymous testing**		
4. **Counselor obtained written informed consent.**		
5. **Counselor addressed partner services and DIS**		
6. **Counselor gave client subject information pamphlet.**		
7. **Counselor assessed whether client was ready to receive results that day.**		
Counseling Skills-While Rapid Test is Running		
8. **Counselor identified client's risk(s) behaviors.**		
9. **Counselor identified client's safer goal behaviors(s).**		
10. **Counselor mainly used non-judgemental language and tone in speaking with client.**		
11. **Counselor asked the client open-ended questions.**		
12. **Counselor maintained strong eye contact and positive body language.**		
13. **Counselor offered options and did not give directives.**		
Counseling Skills-After Rapid Test has Run		
14. **Counselor accurately communicated result to client**		
15. **Counselor allowed time for client to understand result.**		
16. **Counselor made appropriate referrals (one to medical care if prelim. pos).**		
17. **Counselor documented and reviewed a risk reduction plan.**		
18. **Counselor identified date of last exposure and reviewed the window period, including possible retesting if client was negative.**		
19. **Counselor discussed client needs if result is preliminary positive.**		
20. **Counselor accurately completed HIV Test Form-Part 1 (and Part 2 if prelim pos).**		
Rapid Test Lab Operation Skills		
21. **Counselor set up lab space and labeled devices properly.**		

22. **Counselor adhered to all Universal Precautions.**		
23. **Counselor carefully instructed/demonstrated how to collect specimen.** **(For oral swab, continuous circular motion between upper lip and gum to lower lip and gum and remove - One full circle around and no touching tongue, inner cheeks, or roof of mouth)** **Counselor carefully instructed/demonstrated how to collect specimen.** **(For oral swab, continuous circular motion between upper lip and gum to lower lip and gum and remove - One full circle around and no touching tongue, inner cheeks, or roof of mouth)**		
24. **Counselor did not contaminate specimen or device.**		
25. **Counselor did not block holes or move test during processing.**		
26. **Counselor timed the processing accurately.**		
27. **Counselor accurately interpreted and documented test result**		
28. **Counselor recapped all used vials and disposed of used testing supplies in a biohazard container.**		
Total Score:		

Scoring Required to Pass:

-Each section requires 85% correct to pass, and for those items in bold and underlined a score of 10 (adequate) is required. The break down for each section is as follows:

Counseling Skills-Before the Rapid Test is Run = 70 points possible, 60 needed to pass
Counseling Skills-While Rapid Test is Running = 60 points possible, 50 needed to pass
Counseling Skills-After Rapid Test has Run = 70 points possible, 60 needed to pass
Rapid Test Lab Operation Skills = 80 points possible, 65 needed to pass

Name of Person Conducting Observation: _____ _____
Name of person conducting this observation Counselor #

Affiliation of Observer to Counselor (i.e. supervisor, regional coordinator) _____

Signature and Date of Observer Named Above: _____ _____
Signature Date

Write in below the complete physical mailing address where Counselor Certificate should be mailed:

Name of Organization: _____

Street Address: _____City, State, ZIP: _____

Attachment RT-3.11 (maintain on site-for information only)

Louisiana HIV Prevention Counseling, Rapid Testing and Referral Services
Quality Assurance Site Visit Assessment

This form should be completed on the first day of the quality assurance site visit.

SECTION I. Agency Information Assessment Period_____

1. Agency Name_____
2. Name and Title of Supervisor/QA Coordinator_____
3. CLIA Waiver Number_____Expiration Date_____
4. Is CLIA Waiver displayed properly? Yes No
5. Type of Rapid Tests In Use:1)_____2)_____
6. Describe the location where rapid test kits are stored:

   _____

   _____
7. Are Test Device Temperature Logs Maintained on site? Yes No
8. How is the temperature of stored testing devices monitored:

   _____

   _____
9. Review the Test Device Temperature Logs for missing entries, days when temperature was out of range, and any corrective actions taken. Record in the table below.

Date	Describe Problem/Issue	Describe Action Taken (if any)

10. Describe where Rapid Testing Controls are stored:

    _____

    _____
11. Are Rapid Testing Control Logs Maintained on site? Yes No

12. How is the temperature of control kits monitored?

_____

_____

13. Review the Control Kit Temperature Logs for missing entries, days when temperature was out of range, and any corrective actions taken. Record in the table below.

Date	Describe Problem/Issue	Describe Action Taken (if any)

13. Are Daily Test Logs maintained on site? Yes No

14. How well does the site document risk reduction plans in client charts? (review at least 10 charts and indicate what percentage had documented risk reduction plans). _____

_____

15. Are client files maintained appropriately? Yes No

SECTION II. – Comments/Notes/Concerns about rapid testing site.

Use this remainder of this page and the back if needed to make notes about the site's overall rapid testing policies, any additional concerns, and adherences to SHP protocol.

P Number

Attachment RT-3.12 (maintain on site)

Risk Reduction Worksheet

Thank you for participating in our HIV testing program. If you received a **negative** test result that means the test did not detect any HIV antibodies in your body. Antibodies can take up to 3 months to develop if you've been exposed to HIV, so it's important that you know that you could still be infected with HIV even if you tested negative today, especially if you've been exposed in the last 3 months and your body hasn't developed antibodies yet. So get tested regularly, and at least 3 months after having unprotected sex, injecting drugs, or practicing any other behaviors that could put you at risk for HIV, including coming into contact with any of the 4 bodily fluids that HIV can be transmitted through - blood, semen, vaginal fluid, and breast milk.

If you tested **preliminary positive** that means HIV antibodies were detected by the test, and a second rapid test is needed to determine if you need to see a doctor. Please see a medical doctor to learn the best ways to treat the HIV infection; your counselor will help you determine where you might go for medical treatment and can tell you about other types of support available in your area.

During your counseling session today, we talked about behaviors that may put you at risk for HIV and other STDs, and ways to reduce those risks. Below is a summary of your counseling session.

Behaviors	**Action Steps to Reduce Risk**	**Time Frame**
◯ **Having Anal Sex** ◯ **w/ condom** ◯ **w/out condom**		
◯ **Having Vaginal Sex** ◯ **w/ condom** ◯ **w/out condom**		
◯ **Having Oral Sex** ◯ **w/ condom** ◯ **w/out condom**		
◯ **Sharing Needles or Injection Equipment**		
◯ **Having Unprotected Sex with a Person who is HIV+**		
◯ **Other**		

Client Signature/Initial _____ **Counselor Number:** _____